



## THE WEINBERG GROUP INC.

**VIA FACSIMILE**

July 19, 2001

Mr. Les Weinstein  
CDRH Ombudsman (HFZ-5)  
Office of the Center Director  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

Re: PMA990015  
INTERGEL® Adhesion Prevention Solution  
Medical Devices Dispute Resolution Panel

Dear Mr. Weinstein:

This letter is provided to correct facts in the administrative record of the above-referenced PMA as amended. The Sponsor has previously communicated objections to the expanded scope of the Medical Devices Dispute Resolution Panel (MDDRP) meeting, and to the materials provided to panel members in the Panel Pack assembled by the Center for Devices and Radiological Health (CDRH) in anticipation of a June 2001 meeting date (see correspondence from Ellen J. Flannery to Les Weinstein, dated June 21, 2001).

Because a clear understanding of the facts and context within which the planned MDDRP proceedings have been undertaken is necessary for a fair and impartial resolution of this matter, we will appreciate your assistance in ensuring that the following facts and

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information are conveyed to all involved in the review of this PMA as amended.

- (1) CDRH agreed to convene the MDDRP to consider specific scientific issues in dispute with regard to the INTERGEL<sup>®</sup> PMA *as amended* (submission dated June 2, 2000).
- (2) The INTERGEL<sup>®</sup> PMA as amended (submission dated June 2, 2000) contains new data and information and provides for a new intended use for INTERGEL<sup>®</sup>. The new intended use is narrower than that in the original PMA prior to amendment.
- (3) The INTERGEL<sup>®</sup> PMA as amended (submission dated June 2, 2000) has never been the subject of an FDA Advisory Panel meeting. It was not reviewed by the General and Plastic Surgery Devices Panel (which met on January 12, 2000 prior to submission of the amendment on June 2, 2000) or any other Advisory Panel.
- (4) The Sponsor was not informed by the reviewing division that the PMA as amended "would only identify the starting point for a follow-up clinical trial," as stated in the "Lead Reviewer Summary Memo of Lifecore's PMA" appearing in the Panel Pack submitted to the MDDRP on May 30, 2000. The Sponsor submitted this amended PMA for consideration by the reviewing division after meetings with two Division Directors to confirm the scope and contents of the amendment. Among the contents of this amendment *required* by the reviewing Division was a revised Summary of Safety and Effectiveness (to reflect the new intended use and supplemental data and analyses in support thereof).
- (5) The Sponsor submitted a request for dispute resolution to appeal an administrative action by the Office of Device Evaluation (ODE), namely, issuance of a not-approvable letter dated November 15, 2000.
- (6) The Sponsor was not informed, either as an outcome of the review of the PMA as amended or during the course of the current dispute resolution process, that ODE had any unresolved questions regarding statistical issues beyond those noted in the not-approvable letter.
- (7) The AFS scores and shift tables (adnexal adhesion data) provided in the PMA as amended are analyses that were *required* of the Sponsor by ODE (Major Deficiency letter dated December 7, 1999).
- (8) The pivotal trial protocol specifies *three* populations to be considered in the data analysis, only one of which was an "ITT" population. The so-called "ITT" analysis required by FDA was not specified as the primary analysis in the study protocol.



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Thank you for the opportunity to submit this information, and for your continued assistance in this matter.

Very truly yours,



Karen M. Becker, Ph.D.  
Worldwide Managing Director, Healthcare Products  
THE WEINBERG GROUP INC.

cc Ellen J. Flannery, Esq.  
Thomas O. Henteleff, Esq.

